

### **REMARKS/ARGUMENTS**

Claims 1 -104 are pending. In the Office Action dated July 7, 2004, claims 1-104 were rejected. Claims 76 – 94 have been amended. Claims 1 – 74, 79 and 95 – 104 have been canceled, without prejudice. Applicant reserves the right to submit these claims, or claims of similar scope, in a continuation application. No new matter has been added.

#### ***Claim Rejections - 35 USC § 102***

Claims 1-4, 6, 8, 9, 39-42, 44-50, 52-58, 60, 64, 65 and 75 stand rejected under 35 USC § 102(b) as being anticipated by Nablo. These claims have been cancelled without prejudice and the rejection thereof is considered moot.

Claims 1-3, 39-41, 44-49, 52, 54-57, 60, 64, 65 and 75 stand rejected under 35 USC § 102(b) as being anticipated by Rausing. These claims have been cancelled and the rejection thereof is considered moot.

Claims 10, 19, 20, 39, 44-47, 52, 54-56, 60, 64 and 75 stand rejected under 35 USC § 102(e) as being anticipated by Lemke et al. These claims are cancelled without prejudice and therefore the rejection thereof is considered moot. Moreover, applicants make no admission that Lemke is indeed prior art under 35 USC 102(e).

Claim 95 stands rejected under 35 USC § 102(b) as being anticipated by Heffernan et al. Claim 95 is cancelled and the rejection thereof is considered moot.

#### ***Claim Rejections - 35 USC § 103***

Claims 66 and 67 stand rejected under 35 USC § 103(a) as being unpatentable over any of Nablo or Rausing in view of Heffernan et al. These claims have been cancelled and the rejection thereof is considered moot.

Claims 68 stands rejected under 35 USC § 103(a) as being unpatentable over any of Nablo or Rausing in view of Porfano. This claim has been cancelled and the rejection thereof is considered moot.

Claims 5, 7, 43, 51, 59 and 100 stand rejected under 35 USC § 103(a) over Nablo. These claims have been cancelled and the rejection thereof is considered moot. However, the Applicants respectfully assert that the Examiner has not established a prima facie case for a 103(a) rejection. The Examiner asserts that "it is deemed obvious to optimize and even increase the radiation dose based upon the expected level of contamination ..."

The Examiner is under an obligation to not only provide references of such optimization scheme but also have such references supply the motivation for combining such reference(s) with the cited art. Furthermore, applicants make no admission regarding the Examiner's assertion that "the method of Nablo would intrinsically produce the cited pH when sterilizing a parenteral solution". As applicants respectfully submit, the pH of the solution is highly dependent not only on a solution, but also the dosing and interaction of the container material with the solution. There is nothing intrinsic about the resulting pH of a "parenteral solution".

Claims 4-7, 42, 50, 58, 59, 99 and 100 stand rejected under 35 USC § 103(a) over Rausing in Nablo. These claims have been cancelled and the rejection thereof is considered moot.

Claims 10-20 and 22-29 stand rejected under 35 USC § 103(a) over Nablo in view of Lemke et al. These claims have been cancelled and the rejection thereof is considered moot. Moreover applicants repeat their earlier statement regarding the Examiner's need to establish a basis for the assertion regarding optimizing radiation doses.

Claim 21 stands rejected under 35 USC § 103(a) over Nablo and Lemke in view of Porfano et al. Claim 21 is cancelled and the rejection thereof is considered moot.

Claims 10, 11, 12, 19, 20, 22 and 23 stand rejected under 35 USC § 103(a) over Rausing in view of Lemke. These claims have been cancelled and the rejection thereof is considered moot.

Claim 21 stands rejected under 35 USC § 103(a) over Rausing and Lemke et al in view of Porfano et al. Claim is cancelled and the rejection thereof is considered moot.

Claims 24-27 stand rejected under 35 USC § 103(a) as being unpatentable under Rausing and Lemke in view of Nablo. These claims have been cancelled and the rejection thereof is considered moot.

Claim 30 stands rejected under 35 USC § 103(a) over Lemke in view of Porfano. This claim has been cancelled and the rejection thereof is considered moot.

Claims 31-38 stand rejected under 35 USC § 103(a) as being unpatentable over Lemke and Porfano in view of Nablo. These claims have been cancelled and the rejection thereof is considered moot.

Claims 31 and 32 stand rejected under 35 USC § 103(a) as being unpatentable over Lemke and Porfano in view of Rausing. These claims have been cancelled and the rejection thereof is considered moot.

Claims 76-87, 90, 91, 93, 94 and 96 stand rejected under 35 USC § 103(a) over either of Nablo or Rausing and both in view of Heffernan et al. The rejection of these Claims is respectfully traversed. The Examiner asserts that Nablo and Rausing both teach a method of sterilizing a container, transferring the container through a sterile environment to a filler. The Examiner appears to be suggesting that there is a sterilization step in a different environment and then it is transferred into a sterile environment. If that is the Examiner's meaning, the applicants respectfully traverse such an interpretation of the disclosure of the cited references. In both Nablo and Rausing the container is sterilized while being maintained in the same environment which is disclosed as being sterile. There may be physical displacement in the environment, but there is no transferring of the container from one environment to a separate sterile environment.

In addition, applicants note that the Examiner states that Heffernan teaches the art of forming syringes, arranging them in a carrier holder and transferring them to a sterilizing station all while maintaining syringes under Class 100 conditions. Thus, as Examiner has noted, Heffernan does not disclose any transfer of the components into a sterilized Class 100 environment.

In contrast, Claim 76 as currently amended includes, *inter alia*, a step of "transferring the plurality of sterilized syringe bodies into a sterile environment while

maintaining the plurality of syringe bodies in a sterilized condition, said sterile environment comprising an enclosed isolator class 100 environment". Such a step of transferring into an isolator is neither disclosed nor suggested by the cited references and the rejection thereof is respectfully traversed. Claims 77-87, 90, 91, 93, 94 and 96 depend directly or indirectly from allowable Claim 76 as presently amended and therefore are considered allowable.

Claims 88 and 89 stand rejected under 35 USC 103(a) over Nablo, Rausing and Heffernan in view of Porfano et al. Claims 88 and 89 depends indirectly from Claim 76 as presently amended and is therefore is considered allowable. Applicants respectfully submit that Porfano does not disclose the transfer of syringe barrels into a Class 100 isolater, instead Porfano discloses various processes whereby an operator sterilizes syringe barrels in a sterile environment and then, while maintaining the sterile environment, continues to process the syringes in the manners described.

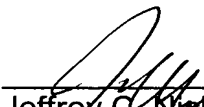
Claim 92 was not specifically rejected but the claim is considered allowable as depending from allowable claim 76 as presently amended.

If it is felt for any reason that direct communication with applicants' attorney would serve to advance prosecution of this case to finality, the Examiner is invited to call the undersigned attorney at the below listed telephone number.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 02-1440.

Respectfully submitted,

Dated: January 7, 2005

  
\_\_\_\_\_  
Jeffrey C. Nichols  
Registration No. 36,879

Baxter International Inc.  
One Baxter Parkway  
Deerfield, IL 60015  
Tel, (847) 948-4922  
Fax. (847) 948-3393